

## **Remarks**

### Amendments to the Claims

Applicants have amended independent claim 1 in an effort to advance prosecution. First, screening for ovarian cancer has been removed from amended claim 1. Second, human has been inserted into the phrase SPHK1 gene copy number to clarify the scope of that term. Finally, the recitation of “control gene copy number” also has been clarified by incorporating language from the specification (see page 8, lines 13-14, page 9, lines 10-12 and especially the paragraph bridging pages 16 and 17 and page 42, lines 6-19). New claims 139-144 also have been added. Claim 139 parallels the language suggested on page 3 of the Office Action where subject matter enabled by the specification is identified. No new matter has been added.

### Rejections Under 35 U.S.C. § 112 ¶ 1

Claims 1-2 and 135-138 stand rejected under 35 U.S.C. § 112 ¶ 1 as failing to comply with the written description requirement and as not being enabled. Applicants respectfully traverse these rejections.

The Office Action asserts that the specification did not reasonably enable the prior claims directed to determining “Sphingosine kinase 1 (SPHK1) gene copy number” but conceded that defining the SPHK1 gene as encoding “an mRNA comprising SEQ ID: 3” would be enabled.

The Office Action also asserts that the rejected claims provide no structural limitation for the phrase “sphingosine kinase 1 (SPHK1) gene.” That phrase is no longer used in claim 1 and has been replaced with the term “sphingosine kinase 1 (SPHK1) human gene.” By directing the claim specifically to the human gene, applicants have focused the claims on well-defined and structurally limited human sequences. The contention in the Office Action (page 12) that “gene sequences very different from the disclosed SEQ ID NO:1” are included in the scope of the claim

is pure speculation, unsupported by any factual evidence. The Office Action impermissibly attempts to place a burden on applicant to demonstrate that the objectively circumscribed claims embracing only the “human gene” in the scope of the recited method are not impermissibly broad. Rather, it is the burden of the Office Action to present concrete evidence, not just speculation, that the invention defined by the claims is not enabled or described. This the Office Action has not done.

As noted, Applicants also have amended claim 1 to embrace the determination of the “Sphingosine kinase 1 (SPHK1) human gene copy number. Thus, amended claim 1 is focused on only the human SPHK1 gene and is no longer directed to any SPHK1 gene. In particular, SEQ ID: 3 is identified as *Homo sapiens* sphingosine kinase 1 (SPHK1) coding sequence. The amendment to claim 1 thus overcomes any potential deficiencies the Office Action had with the previous claim language.

By focusing the claims on the human gene, applicants also have overcome the contention in the Office Action (page 13) faulting the application for failing to allow one to identify “genes from another organism.” That contention also becomes irrelevant in view of amended claim 1 and new claim 139. In particular, new claim 139 is presented and recites that the SPHK1 gene encodes an mRNA comprising SEQ ID:3 as suggested in the Office Action.

The Office Action also finds fault with the recitation of “corresponding tissue” conceding that the specification “defines ‘control sample’ as a sample obtained from a cancer-free population.” The Office Action goes on to intimate that if the phrase “ ‘a corresponding tissue’ is amended to specify ‘a control sample of the same tissue type as the test sample’ ” the claim language would be acceptable. Applicants note that the concepts of a control sample and of

“control gene copy number” are repeatedly addressed throughout the specification. See *inter alia*, page 8, lines 13-14, page 9, lines 10-12 and especially the paragraph bridging pages 16 and 17 and the paragraph on page 42, lines 6-19 of the application. Given the high level of skill in the art for the subject matter defined by the pending claims, the reference to “control gene copy number” in claim 1 is clearly described and enabled by the presented description. In addition, newly presented claim 139 provides the “same tissue type” language suggested by the Office Action.

The Office Action also argues that the “reporting of ‘-fold amplification’ is not clear within the specification.” Applicants disagree. Page 34 of the application clearly equates the phrase “3.0 fold or more copies” with the statement “a copy number greater than or equal to 3.0.” Thus, the phrases “at least four-fold,” “at least five-fold,” and “at least 10-fold” respectively mean -- a copy number greater than or equal to 4.0--, -- a copy number greater than or equal to 5.0— and -- a copy number greater than or equal to 10.0--. Armed with this description, one skilled in the art understands the term to refer to an absolute number of copies of the gene in a sample.

#### Rejection Under 35 U.S.C. § 102(b)

The Final Office Action maintains the rejection of claims 1 and 2 under 35 U.S.C. § 102(b) over Suehiro.<sup>1</sup> Applicants respectfully traverse the rejection.

A reference cited under 35 U.S.C. § 102 must expressly or inherently describe each element set forth in the rejected claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Independent claim 1 has been amended to

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<sup>1</sup> Suehiro *et al.*, “Genetic Aberrations Detected by Comparative Genomic Hybridization in Ovarian Clear Cell Adenocarcinomas,” *Oncology* 59, 50-56, 2000.

remove “ovarian” cancer from the scope of the recited screen and new independent claim 139 does not include ovarian cancer.

The Office Action contends that Suchiro’s disclosure of amplification of the genetic region 17q25-ter and its apparent association with ovarian cancer is the same as a disclosure of amplification of the SPHK1 gene’s association with this disease. While applicants do not concede this to be the case, applicants have amended the claims to remove ovarian cancer from the scope of the recited screen. As a result, the claim can not be anticipated by Suchiro.

Please withdraw the rejection.

Applicants believe the foregoing amendments and arguments have overcome the bases for rejecting the pending claims presented in the Office Action.

Please withdraw the rejections.

Respectfully submitted,  
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Dated: August 1, 2007

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